4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-1037]

Fresenius USA, Inc., et al.; Withdrawal of Approval of 216 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the *Federal Register* of October 22, 2021. The document announced the withdrawal of approval of 216 abbreviated new drug applications (ANDAs) from multiple applicants, as of November 22, 2021. The document was published with an incorrect date. In addition, the document indicated that FDA was withdrawing approval of ANDA 075941, Strontium Chloride SR–89 Injection, 1 millicurie/milliliter, held by Bio-Nucleonics, Inc., 1600 Market St., Suite 13200, Philadelphia, PA 19103, for repeated failure to submit annual reports. Before FDA withdrew the approval of this ANDA, the application holder informed FDA that it submitted annual reports for ANDA 075941. Therefore, FDA rescinds its withdrawal of approval of ANDA 075941. The approval of ANDA 075941 is still in effect.

FOR FURTHER INFORMATION CONTACT: James Hanratty, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993-0002, 240-402-4718, James.Hanratty@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Corrections

In the *Federal Register* of Friday, October 22, 2021 (86 FR 58675), in FR Doc. 2021-23075, the following corrections are made:

1. On page 58675, in the second column, correct the DATES section to read: "DATES: Approval is withdrawn as of October 22, 2021."
2. On page 58679, in the table, remove the entry for ANDA 075941.

Dated: January 12, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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